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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,288	05/09/2002	Paolo Pevarello	218195USOPCT	9829

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EXAMINER

ANDERSON, REBECCA L

ART UNIT PAPER NUMBER

1626

DATE MAILED: 08/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/049,288	Applicant(s) PEVARELLO ET AL.	
	Examiner Rebecca L Anderson	Art Unit 1626	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other:  |

### DETAILED ACTION

Claims 1-23 are currently pending in the instant application and are subject to a lack of unity requirement.

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Due to the numerous and widely divergent variables in substituents R, R3, and R2, the numerous methods of preparation and the numerous and widely divergent methods of use present, a precise listing of inventive groups cannot be made. The following groups are exemplary:

Group I, claim(s) 1-7, 13 and 14 drawn to a method of treating Alzheimer's disease with the compound of formula (I) wherein R is C1-C6 alkyl optionally substituted as found in the claims, R1 is  $-(CH_2)_n-R_3$ , n is 1 and R3 is phenyl and R2 is hydrogen.

Group II, claim(s) 1-7, 11-13 and 14 drawn to a method of treating squamous cell carcinoma with the compound of formula (I) wherein R is C1-C6 alkyl optionally substituted as found in the claims, R1 and R2, together with the nitrogen atom to which they are bonded form piperazine.

Group III, claim(s) 8-10 and 13 drawn to a method of treating Alzheimer's disease with the compounds wherein the pyrazole is substituted in the 3 position by C3-C6 alkyl, substituted in the 5 position by N'-[2-(1-piperidinyl)ethyl]urea.

Group IV, claim(s) 15, 19, 20 and 23 drawn to the products of formula (I) wherein wherein R is C1-C6 alkyl optionally substituted as found in the claims, R1 is  $-(CH_2)_n-R_3$ , n is 1 and R3 is phenyl and R2 is hydrogen.

Group V, claim(s) 16-17 and 20 drawn to the products of formula (I) wherein wherein the pyrazole is substituted in the 3 position by C3-C6 alkyl, substituted in the 5 position by N'-[2-(1-piperidinyl)ethyl]urea.

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Group VI, claim(s) 15, 19, 18, 20 and 23 drawn to the products of formula (I) wherein R is C1-C6 alkyl optionally substituted as found in the claims, R1 and R2, together with the nitrogen atom to which they are bonded form piperazine.

Group VII, claim(s) 21 drawn to a process for the preparation of the compound of formula (I) as found in claim 15 wherein R is C1-C6 alkyl optionally substituted as found in the claims, R1 is  $-(CH_2)_n-R_3$ , n is 1 R3 is phenyl and R2 is hydrogen.

Group VIII, claim(s) 21 drawn to a process for the preparation of the compound of formula (I) as found in claim 15 wherein R is C1-C6 alkyl optionally substituted as found in the claims n is 1, R3 is piperidiny, and R2 is hydrogen.

Group IX, claim(s) 22 drawn to a process for the preparation of the compound of formula (I) wherein R is C1-C6 alkyl optionally substituted as found in the claims, R1 is  $-(CH_2)_n-R_3$ , n is 1 R3 is phenyl and R2 is hydrogen.

Group X, claim(s) 22 drawn to a process for the preparation of the compound of formula (I) wherein R is C1-C6 alkyl optionally substituted as found in the claims n is 1, R3 is piperidiny, and R2 is hydrogen.

*Note: dependent claims 8-10, 13, 12-17 and 20 contain compounds that do not fall within the definition of the compound of formula (I) as found in the claims from which they depend. R in claims 1 and 15 is optionally substituted C1-6 alkyl, aryl or arylalkyl except when n is 0 and R2 is hydrogen, then R must be C3-C6 cycloalkyl. However, claims 8-10, 13, 12-17 and 20 contain compounds wherein R is C3-C6 cycloalkyl when n is not necessarily 0 and R2 is not necessarily hydrogen, which lacks antecedent basis in the base claims. For example, the compound N-(3-cyclopropyl-1H-pyrazol-5-yl)-N'-[2-(1-piperidiny)ethyl]urea (the 1<sup>st</sup> mentioned compound in claim 13) has the values R is cyclopropyl, n is 2 and R2 is hydrogen, which does not fall within the definitions for R as found in the base claim 1 because R can only be C3-C6 cycloalkyl when n is 0 and R2 is hydrogen.)*

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted. Again, this list is not exhaustive as it would be impossible under the time constraints due to the sheer volume of subject matter instantly claimed. Therefore, applicant may choose to elect a single invention (a product, a method of preparation and a method of use) by identifying another specific embodiment not listed in the exemplary groups of the invention and examiner will endeavor to group the same. The applicant may also choose to elect a

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single disclosed species along with a single method of use and the examiner will endeavor to create a group comprising the elected species.

The claims herein lack unity of invention under PCT rule 13.1 and 13.2 since, under 37 CFR 1.475(a) Group I -Group X lack unity of invention since under 37 CFR 1.475:

Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features...those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The technical features corresponding to the claims are the 1,2 diazole and the urea at the 3 position of the 1,2-diazole. These technical features are not special technical features because they fail to define a contribution over the prior art as can be seen by Vogel et al. which discloses the compound 15 in scheme 4 on page 763 and also by US Patent No. 6,043,246 which discloses the compounds of formula (I). Therefore claims 1-23, are not so linked as to form a single general inventive concept and there is a lack of unity of invention because they lack a special technical and the technical features present fail to define a contribution over the prior art. The variables on the 1,2-diazole and on the urea at the 3 position of the 1,2-diazole vary extensively and when taken as a whole result in vastly different compounds. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper. Additionally, the vastness of the claimed subject matter, and the complications in understanding the claimed subject matter imposes a serious burden on any examination of the claimed subject matter.

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Therefore, since the claims do not relate to a single general inventive concept under PCT Rule 13.1 and lack the same or corresponding special technical features, the claims lack unity of invention and should be limited to only a product, a process for the manufacture of the said product, or a method of use.

Furthermore, in regards to groups I-X even if unity of invention under 37 CFR 1.475(a) is not lacking, under 37 CFR 1.475(b) a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and a process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

And, according to 37 CFR 1.475(c)

if an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b), unity of invention might not be present.

Therefore, since the claims are drawn to more than a product, a process, and a method of use, and according to 37 CFR 1.475 (e)

the determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

The claims, therefore, lack unity of invention.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (703)

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605-1157. Mrs. Anderson can normally be reached Monday through Friday 7:00AM to 3:30PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph McKane, can be reached at (703) 308-4537.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone numbers are (703) 308-1235 and (703) 308-0196.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45AM to 4:45PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4242, (703) 305-3592, and (703) 305-3014.



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